K091512

SYBRON DENTAL SPECIALTIES

OCT 30 2009

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7602 - Phone
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Wendy Garman - Contact Person

Date Summary Prepared: May 2009

Device Name:

- Trade Name – *Build-It Light Cure*
- Common Name – Dental Composite Restorative Material
- Classification Name – Tooth Shade Resin Material, per 21 CFR § 872.3690

Devices for Which Substantial Equivalence is Claimed:

- *Clearfil Photo Core,* Kuraray Medical Inc.

Device Description:

Build-It light Cure is a line extension to the current two-component dual curable Build-It FR core material. It is available in a translucent shade only. The depth of cure of the material is > 7 mm to facilitate the bulk filling. The formulation of the material utilizes BisGMA free methacrylate resin mixture and the fillers are essentially the combination of conventional bariumborosilicate glasses with a little sodium fluoride. The handling character of the material facilitates easy adaption to the tooth.

Intended Use of the Device:

Build-It Light Cure is a translucent, light activated composite material designed for core build ups. It is used as core-building material on vital teeth as well as on non-vital teeth, in combination with or without a dental post. It may also be used as a final restorative filling material.

Substantial Equivalence:
Build-It Light Cure is substantially equivalent to other legally marketed devices in the United States. *Build-It Light Cure* functions in a manner similar to *Clearfil Photo Core*, currently marketed by Kuraray Medical Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Pentron Clinical Technologies, LLC
C/O Ms. Wendy Garman
Director of Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

OCT 30 2009

Re: K091512
Trade/Device Name: Build-It Light Cure
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: September 23, 2009
Received: September 30, 2009

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: *Build-It Light Cure*

Indications For Use:

Build-It Light Cure is a translucent, light activated composite material designed for core build ups. It is used as core-building material on vital teeth as well as on non-vital teeth, in combination with or without a dental post. It may also be used as a final restorative filling material.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091512